

REMARKS

Support for new claim 13 can be found for example in original claim 1.

The first Rejection Under 35 U.S.C. § 112, first paragraph

The Office Action alleges that the disclosure does not provide enablement for R^{1a}, R^{1b}, R^{2a}, R^{2b}, R^{4a}, R^{4b}, R⁵, R⁸, R¹⁰, and R¹¹. Citing several of the factors from *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the Examiner alleges that these groups exhibit a wider Markush grouping of radicals than those radicals synthesized. In this respect the rejection presents no rationale as to why these claims are not enabled, but merely states conclusions. Specifically, it alleged that the application is not enabled, the claims are broader than the scope of enablement, and the specification lacks sufficient direction and guidance. These are mere conclusions. The rejection fails to set forth any rationale or evidence for the conclusion of non-enablement.

However, even before one gets to the *Wands* factors, the courts have placed the burden upon the PTO to provide evidence shedding doubt on the disclosure that the invention can be made and used as stated. The disclosure "*must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statement contained therein, which must be relied on for enabling support." See *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). No such evidence or reason for doubting Applicants' disclosure is provided.

Doubt has been held reasonable where, for example, the invention has been characterized as "highly unusual," *In re Houghton*, 433 F.2d 820 (CCPA 1970), as "incredible," *In re Citron*, 325 F.2d 248, (CCPA 1963); or as "too speculative," *In re*

Eltgroth, 419 F.2d 918 (CCPA 1970). The preparation of compounds having a variety of heterocyclic groups is not objectively doubtful, i.e., not “highly unusual,” “incredible,” and/or “too speculative.” Thus, the rejection should be withdrawn for this reason alone.

Nevertheless, applicants address the *Wands* factors recited by the Office Action.

The court in *Wands* held that the test for enablement is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

The court in *In re Angstadt*, 10 USPQ 214, 219 (CCPA 1979), where the court acknowledged the art involved, i.e., catalysis, to be unpredictable, also said that the test for enablement is not whether any experimentation is needed, but whether or not that experimentation is undue. In addition, even a considerable amount of experimentation or complex experimentation is permissible if it is routine. See, e.g., *Ex parte Jackson*, 217 USPQ 804, 807 (POBA 1982).

The specification provides ample guidance on how the claimed compounds are prepared, i.e., both broad teachings as well as specific reaction schemes to achieve the claimed compound, as well as specific examples are provided, in addition to pointing to references that teach the preparation of the claimed compounds. The specification, for example, provides 58 pages of general synthesis information (e.g., pages 19-77). Thereafter, the specification provides, for example, 199 pages of specific examples (e.g., pages 82-281). No rationale or evidence was provided by the Patent Office as to why one of ordinary skill in the art based on this vast amount of disclosure and guidance would be unable to prepare without undue experimentation the claimed compounds.

Additionally, “the [enablement] requirement is satisfied if, given what they [those of ordinary skill in the art] already know, the specification teaches those in the art enough that they can make and use the invention without ‘undue experimentation.’” See *Amgen v Hoechst Marion Roussel*, 65 USPQ2d 1385 (Fed. Cir. 2003). Making the compounds of the claimed invention would be routine for those of ordinary skill in the

art since they are prepared analogously to known processes. See, for example, *Spectra-Physics v Coherent*, 827 F.2d 1524, 3 USPQ2d 1737 (Fed. Cir. 1987) ("A patent need not teach, and preferably omits, what is well known in the art"); *In re Howarth*, 654 F.2d at 105, 210 USPQ 689 (CCPA 1981) ("An inventor need not ... explain every detail since he is speaking to those skilled in the art."); *In re Gay*, 309 F.2d 769, 774, 135 USPQ 311 (CCPA 1962) ("Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be.")

Explicitly providing examples for preparing species having each possible group is not necessary to enable the full scope of the claims. There is no such requirement imposed by law. See, for example, *In re Angstadt*, 537 F.2d at 502-03, 190 USPQ 214 (CCPA 1976) (deciding that applicants "are *not* required to disclose *every* species encompassed by their claims even in an unpredictable art"); *Utter v Hiraga*, 845 F.2d at 998-99, 6 USPQ2d 1714 (Fed. Cir. 1988) (holding that a specification may, within the meaning of Section 112, Para. 1, enable a broadly claimed invention without describing all species that claim encompasses).

Instead, there is no requirement for any examples. See, for example, *Marzocchi*, supra, stating "an enabling teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance." The MPEP also states "compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does, not turn on whether an example is disclosed." See MPEP § 2164.02.

The PTO has failed to meet its burden of establishing that the disclosure does not enable one skilled in the art to make the compounds recited in the claims. Instead of relying on proper probative evidence, the rejection is improperly based on the bare allegation that the disclosure does not provide enablement to all of the claimed C₇₋₂₀ aralkyl groups. No evidence has been presented which would demonstrate that the guidance provided by the specification or what is already known in the art is inadequate to enable the preparation of the claimed compounds without undue experimentation. In light of the disclosure, taken in combination with knowledge possessed by one of ordinary skill in the art, sufficient guidance is provided to objectively enable one of

ordinary skill in the art to make and use the claimed invention, including those compounds exhibiting C₇₋₂₀ aralkyl groups, using no more than routine experimentation.

Thus, the rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

The second Rejection Under 35 U.S.C. §112, Second Paragraph

The rejection of claims 2-7 and 12 under 35 U.S.C §112, second paragraph is respectfully traversed.

With regards to the phrase “the molecule is identical to naturally occurring epothilone A or B”, naturally occurring epothilones are well known to one skilled in the art. Additionally, the first paragraph of Applicants specification provides a structure and a reference to naturally occurring epothilone A or B. Thus, the meaning of the term is fully and clearly disclosed. The claims set forth clearly how the structure is modified from the known naturally occurring structure.

Accordingly, it is urged that the present claims are clearly supported by the disclosure and the rejection under 35 U.S.C §112, second paragraph, should be withdrawn.

The Rejections Under 35 U.S.C. §103 over CA132:293587r and Nicolaou et al.

The rejections under 35 U.S.C. § 103, over CA132:293587r and Nicolaou et al. are respectfully traversed.

Applicants traverse the rejection on the grounds that a compound meeting all the elements of applicants claims is not specifically identified nor is there motivation or


guidance to alter the teaching of Nicolaou to arrive at a compound meeting all the elements of applicants claimed invention. Claim 1 specifically recites that if -D-E- are $\text{CH}_2\text{-CH}_2\text{-}$ and Y=O then R^{2a} and R^{2b} can not be hydrogen or methyl.

There is no motivation in Nicolaou et al. to alter the structure to arrive at the genus of the present invention. For example, the compounds of CA132:293587r and Nicolaou et al. do not include or suggest materials wherein the R^{2a} or R^{2b} groups are ethyl.

In view of the above remarks, it is respectfully submitted that CA132:293587r and Nicolaou fails to suggest Applicants' claimed invention. Withdrawal of the rejection under 35 U.S.C. §103 is respectfully requested.

In view of the above remarks, it is respectfully submitted that the claims of the application are fully supported by the specification and as such are in order for allowance.

Respectfully submitted,


Jennifer J. Branigan
Patent Agent (Reg. No. 40,921)

John Sopp (Reg. No. 33,103)
Attorney for Applicants

MILLEN, WHITE, ZELANO & BRANIGAN, P. C.
Arlington Courthouse Plaza I
2200 Clarendon Boulevard, Suite 1400
Arlington, Virginia 22201
Direct dial: (703) 812-5305
Internet address: jbranigan@mwzh.com

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